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**Johnson & Johnson**  
CONSUMER PRODUCTS, INC.  
SKILLMAN, NJ 08558-9418

JUN 21 2002

Jonathan Wilkin, MD, Director  
Division of Dermatologic and Dental Drug  
Products  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Drug Evaluation V, HFD-540  
Attn: DOCUMENT CONTROL ROOM N115  
9201 Corporate Boulevard  
Rockville, MD 20850

IND 21,542

Miconazole Nitrate Diaper Rash  
Ointment

Serial No.: 019

Transfer of Ownership

Dear Dr. Wilkin:

Reference is made to the Investigational New Drug 21,542 for Miconazole Nitrate Diaper Rash Ointment and to 21CFR314.72 Transfer of Ownership.

This correspondence will serve as the official notification of the Transfer of Ownership of the referenced Investigational New Drug from:

Johnson & Johnson Consumer Companies, Inc.  
199 Grandview Road  
Skillman, New Jersey 08558

To

Barrier Therapeutics  
100, Overlook Center (2<sup>nd</sup> Floor)  
Princeton, NJ 08540

and will be effective the date of this correspondence.

This transfer of ownership includes:

- Transfer of a complete copy of the filed IND and all applicable subsequent filings.
- Transfer of all agreements, promises and conditions made by the former application holder to Barrier Therapeutics.

All future applicant inquiries should be forwarded to the new IND holder, Barrier Therapeutics.

If you have any questions, I can be reached at (908) 874-1239 or Stephanie Davis can be reached at (908) 874-2410.

Thank you.

Sincerely,



George Latyszonek  
Director, Regulatory Affairs

# **BARRIER THERAPEUTICS, INC.**

100 OVERLOOK CENTER, 2<sup>ND</sup> FLOOR

PRINCETON, NJ 08540

TEL: 609-375-2200

FAX: 609-375-2660

June 21, 2002

Jonathan Wilkin, MD, Director  
Division of Dermatologic and Dental Drug  
Products  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Drug Evaluation V, HFD-540  
Attn: DOCUMENT CONTROL ROOM N115  
9201 Corporate Boulevard  
Rockville, Maryland 20850

**IND 21,542**

**Miconazole Nitrate Diaper Rash  
Ointment**

**Serial No.: 020**

**Acceptance of IND Ownership and  
Responsibility**

Dear Dr. Wilkin:

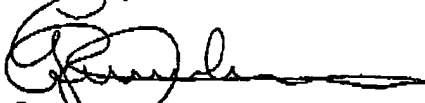
This is to inform you that effective the date of this letter Barrier Therapeutics accepts the ownership of and responsibility for the management of Investigational New Drug Application 21,542, Miconazole Nitrate Diaper Rash Ointment. Barrier Therapeutics has access to a complete copy of IND 21,542 and correspondence pertaining thereto.

Please address future correspondence concerning this Investigational New Drug Application to me at :

Barrier Therapeutics  
100, Overlook Center (2<sup>nd</sup> Floor)  
Princeton, NJ 08540

Should you have any questions, please contact me directly at (609) 375-2280.

Sincerely,



Geert Cauwenbergh, Ph.D.  
Chief Executive Officer

Enclosure  
Form FDA 1571